

### REMARKS/ARGUMENTS

Claim 17 is amended. Claims 141-152 are added. Claims 1-16 are cancelled. Claims 21-33, 35-54, 67-78 and 85-140 are withdrawn. Claims 17-20, 34, 55-66, 79-84, 141-152 remain in the application.

Applicants hereby request further examination and reconsideration of the application in view of the discussion below.

The Examiner has acknowledged Applicant's election with traverse of group I, species I in the reply filed on June 1, 2006 and has made it final. Applicants have withdrawn Claims 21-33, 35-54, 67-78 and 85-140 from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

The Examiner has rejected claims 17-20 and 34 under 35 U.S.C. 103(a) as being unpatentable over Alcamo (3,123,077) in view of Granger (5,123,911). The Examiner submits that Alcamo discloses a barbed suture with helically positioned barbs. However, the ratio of the suture diameter to needle diameter is not disclosed. Additionally, the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. Once the cuts are made after the suture has been twisted, the suture is unwound. The resulting pattern of the cuts is merely a multiple spiral. Since Alcamo discloses a suture with barbs which are in multiple spirals, this limitation is met. As for the specific spiraled angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spiraled angle of the Alcamo's barbs.

The Examiner further contends that Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. This ratio would fall within the claimed ratio. It would have been obvious to have attached the barbed suture of Alcamo to an equal diameter suture needle, in order to facilitate the attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue.

#### **The Examiner has failed to meet his burden of proof of obviousness.**

Applicants respectfully disagree with the Examiner's rejection of these claims on this basis. Applicants submit that the Examiner has not established a prima facie case of obviousness. Three criteria must be met:

1. there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
2. there must be a reasonable expectation of success; and
3. the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Section 2143. MPEP.

Applicants submit that there is no motivation or suggestion in either reference cited by the examiner to modify or combine the reference teachings which would result in the claimed invention. Alcamo is directed to surgical sutures having outwardly projecting elements. Granger et al. (US 5,123,911) is directed to a method for attaching a needle to a suture. There is no suggestion or teaching to use barbed sutures with the Granger invention with a needle to suture diameter ratio of 3:1 or less. Neither Granger nor Alcamo address or identify any relevance of a needle to suture diameter ratio in combination with the needle and barbed suture assembly. Accordingly, a conclusion that the cited references render the claimed invention obvious is without merit and should be withdrawn.

Applicants submit that even if there were a teaching to combine the cited references, Granger actually suggests moving away from the teaching of the present invention. In describing the various ways in which the suture can be attached to the needle, Granger discusses reducing the diameter of the suture tip by dipping it in resin which may be desirable "to prevent blooming of the suture,...to rigidify the end of the suture to facilitate handling during attachment, and to allow a suture of larger diameter, e.g., a suture diameter equal to the diameter of the needle to which it is to be attached, to be more efficiently attached to the needle using the shrinkable tubing of the present invention". Col. 7, lines 14-21. If the suture diameter were larger than the needle diameter, the needle to suture diameter ratio would be less than one, which is clearly outside the scope of the present invention. Because the prior art does not teach or suggest the claims of the present invention, the Examiner has failed to meet the first element in his burden of proving obviousness under Section 103.

Further, even there is no expectation of success in combining the cited references to result in the claimed invention. The Federal Circuit has set forth the standard regarding the analysis to be used in determining appropriateness of combining references.

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under Section 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success... Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Even if the cited references were combined, the prior art does not provided any indication of reasonable success of the imagined combination. Applicants cited both references in its application and thus were aware of the teachings of both references. Yet, Applicants specification includes numerous tables which address several variables relating to the design of barbed sutures. These variables include cut angle, cut depth, cut length, cut distance, spiraled angle, needle diameter and suture diameter. Applicants varied these factors in a number of

experiments, some of which are disclosed and described in the application in Tables 7A-Z and Table 13A & B. The extent of the experimentation conducted by applicants clearly indicates that the resulting effectiveness of the combination of a needle and barbed suture was not an obvious one. Further, the results of varying the barbed suture diameter relative to the needle diameter were not obvious. If the applicants, who were certainly skilled in the art at the time the invention was made did not know with relative certainty the effective performance of assemblies having varied needle to suture diameter ratios, it is erroneous to conclude that the result of varied combinations would be obvious.

In failing to meet his *prima facie* case of obviousness, the Examiner has further failed to demonstrate that the cited prior art teaches or suggests all claim limitations. Alcamo does not show a multiple spiral barb disposition as contended by the examiner. Twisting the suture body prior to cutting yields a single row of barbs extending in a spiral fashion along the length of the suture body. As such, a plane perpendicular to the suture body and cutting transversely through the suture and intersecting any portion of a barb will not intersect any portion of a second barb. This barb configuration is not shown by Alcamo. Moreover, since Alcamo does not show a multiple spiral barb disposition, Alcamo cannot show a spirality angle.

Applicants further submit that none of the references teach or suggest any needle to suture diameter ratios. Even if it could be argued that Granger teaches a 1:1 needle to suture ratio, which applicants vigorously dispute, such a ratio would not render the subject claims obvious. Here the Examiner submits that Granger teaches a needle to suture diameter ratio of 1:1 merely because the needle and suture are of the same relative proportions in the drawings. However, Applicants submit that Granger does not address the challenges associated with varied needle to suture ratios as they apply to barbed suture applications. As applicants point out in their specification, the needle to suture diameter ratio is important in all applications. While, use of a larger needle is typically used for tougher tissues such as bowel and muscle, the needle to suture ratio should still be in the claimed range to operate effectively. Similarly, delicate tissues require the use of a smaller diameter needle and thus, according to the present invention would also require a smaller diameter barbed suture to operate effectively (paragraph 205 of the specification).

Recently, the courts have addressed claim ranges. In one case, the Federal Circuit allowed claims where there was a slight overlap in a temperature range disclosed in a piece of prior art. In *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ2d 1417 (Fed. Cir. 2006), the court addressed the issue of claimed ranges as they related to chemical process claims. The claim range of claim 1 was "between 330 and 450° C. The examiner had rejected the claim based on a prior art reference that disclosed a temperature range of 150 to 350° C. The Federal Circuit reversed the district court finding of anticipation based on this reference by stating that "the disclosure of a range does not constitute the specific disclosure of the endpoints of that range. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points. *Id.* at 1424. The court went on to state that "although there is a slight overlap [in the ranges], no reasonable fact finder could determine that this overlap describes the entire claimed range with sufficient specificity to anticipate this limitation of the claim." *Id.*

Atofina is directly applicable to the facts of the present case. The Examiner has cited Granger on the basis that Granger teaches a needle to suture ratio of 1:1. Applicants submit that Granger does not teach such a ratio because the identification of the needle to suture ratio is not disclosed or addressed in Granger. Even if Granger were to disclose a needle to ratio of 1:1, such a singular point in view of applicants' claimed ranges of needle to suture ratios does not render the subject claims obvious. No reasonable fact finder would determine that a singular needle to suture diameter ratio of 1 as purportedly disclosed in Granger describes the entire claimed range with sufficient specificity to render the subject claims obvious.

In conclusion, the Examiner has failed to present a prima facie case of obviousness in the present case. The cited prior art does not teach or suggest the claims at issue. Further a fictional combination of the cited references would not result in the present invention. There was no disclosure in the cited references that would have given one of ordinary skill in the art a reasonable expectation of success in selecting the parameters disclosed in the claims at issue. In particular, there was no disclosure in the cited references that would indicate that use of the claimed needle to suture diameter ratio of 3:1 or less would meet with expected success. Finally, the prior art does not teach or suggest all of the claim limitations. None of the cited references addresses the issue of needle to suture diameter ratios. For the reasons set forth above, claims 17-20 and 34 are not obvious and should be allowed as presently presented.

The Examiner has rejected Claims 55-66 and 79-84 under 35 U.S.C. 103(a) as being unpatentable over Alcamo in view of Granger, as applied above, and further in view of Buncke (US 5,931,855). The Examiner submits that Alcamo as modified by Granger makes obvious the invention as claimed with the exception of the suture materials. The Examiner further submits that Buncke discloses the claimed suture materials. The Examiner concludes that it would have been obvious to have made the Alcamo/Granger suture out of the suture materials disclosed by Buncke. The Examiner submits that for certain procedures, it would be desirable for the suture to be non-absorbable and others it would be more desirable for the sutures to be absorbable.

Applicants respectfully disagree with the Examiner's rejection of claims 55-66 and 79-84. As stated above, Applicants submit that the Examiner's basis for rejection rests solely on the erroneous position that the combination of cited prior art will render the claims of the present invention obvious. There is no teaching or suggestion to combine the cited references. In addition, even if it were conceded by applicants that the cited references in combination taught or suggested a needle/barbed suture combination, there is no teaching or suggestion in the cited prior art to focus on the effect of the relative diameters of the needle and suture and result in the claimed range of 3:1. Alcamo, Granger or Buncke do not focus on the relative diameters of the needle and suture. Nor do any of the cited references discuss the impact of the relative diameters as it related to the ultimate assemblies effective performance. Thus, the combination of Alcamo, Granger and Buncke does render claims 55-66 and 79-84 obvious.

The Examiner has rejected claims 17-20, 34, 55-66 and 79-84 under 35 U.S.C. 103(a) as being unpatentable over Buncke in view of Granger. The Examiner contends that Buncke discloses a barbed suture with helically positioned barbs. The Examiner states that the suture is

formed of absorbable or non-absorbable material. The Examiner admits that the ratio of the suture diameter to needle diameter is not disclosed. The Examiner further admits that the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. The Examiner states that once the cuts are made after the suture has been twisted, the suture is unwound. The Examiner further states that the resulting pattern of the cuts is merely a multiple spiral. The Examiner concludes that since Buncke discloses a suture with barbs which are in multiple spirals, this limitation is met. The Examiner further concludes that as for the specific spiraled angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spiraled angle of the Buncke's barbs. The Examiner further states that Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. The Examiner further states that this ratio would fall within the claimed ratio. The Examiner concludes that it would have been obvious to have attached the barbed suture of Buncke to an equal diameter suture needle, in order to facilitate the attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue.

Applicants disagree with the Examiner's rejection of claims 17-20, 34, 55-66 and 79-84. As set forth above, applicants believe that the Examiner has not met his burden of proof in establishing a prima facie case of obviousness. The cited references do not provide any motivation to combine the teachings of the cited prior art which would result in the claimed invention. In addition, there was no evidence that any such combination would have a reasonable expectation of succeeding to accomplish what applicant has accomplished in the claimed invention. Finally, the cited prior art does not teach or suggest all the limitations set forth in the claimed invention. In particular, there is no teaching or suggestion in any of the references of a multiple spiral barb disposition or spirality angle. Nor is there a teaching or suggestion to adopt a needle to suture ratio of 3:1. Following the teaching of Atofina, a claimed range is not obvious where a reasonable fact finder could not determine that any possible overlap describes the entire range. *Id.* at 1424. Granger makes no mention of the importance of the relative needle to suture diameters. Thus, a reasonable fact finder would not conclude from Granger that a needle to suture diameter ratio range of 3:1 or less was disclosed in that reference. Accordingly, rejection of claims 17-20, 34, 55-66 and 79-84 is in error and should be withdrawn, and all pending claims as presently presented should be allowed.

Applicants have added new independent claims 141-143. The new claims are directed to needle to suture diameter ratios of about 3:1 to 1.47:1. These have support in the specification. See para. 203 of the specification. Thus, applicants are not introducing any new matter. Further, for the same reasons stated above, applicants submit these claims are novel, non-obvious and entitled to allowance in their presently presented form.

Applicants have added new dependent claims 144-152. The new claims are directed to the shape of the cross-section of the suture body. These have support in the specification. See para. 49 and 50 of the specification. Thus, applicants are not introducing any new matter.

Further, for the same reasons stated above, applicants submit these claims are novel, non-obvious and entitled to allowance in their presently presented form.

For all the reasons set forth above, Applicants believe all pending claims are non-obvious and should be allowed in their presently pending form. A notice of allowance to all pending claims is courteously solicited. In the event any issues remain, the Examiner is invited to contact the undersigned attorney to resolve the same.

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Respectfully submitted,

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